

### **REMARKS**

In the Office Action mailed October 6, 2005, Claims 35-61 were pending for consideration. All of the claims were objected to and rejected on various statutory grounds, each of which is addressed in turn below.

By the present amendment, Claims 38 and 45 have been amended to correct typographical errors. Applicants respectfully submit that no new matter is added thereby. Additionally, Claim 50 has been amended in a manner as suggested by the Examiner during the interview of September 12, 2005. Furthermore, Claims 36-46 have been amended as outlined below. Support for these amendments can be found *inter alia* on page 13 lines 9-28. Claim 53 has been amended to maintain consistency with the use of the term “about.” Also, Claims 62-64 have been added. Support for these claims can be found on page 11, lines 15-16, and page 20, lines 2-4. Applicants submit that no new matter has been added thereby.

The specification has also been amended to correct the priority of the application, as well as to correct various objections noted by the Examiner.

It is to be understood that all amendments have been made solely for the purpose of expediting prosecution of the present application, and without conceding the correctness of the Examiner’s rejection. Accordingly, Claims 35-64 remain pending for consideration in the present application. Applicants respectfully submit that the present claims are allowable over the Patel reference, and that the rejections in view thereof are now moot.

#### **Claim and Specification Objections:**

Claim 42 has been objected to because of a minor informality noted by the Examiner. The claim has been amended to correct this informality.

Claims 38 and 45 have been amended to correct misspellings of the word “nicotinate.”

The Applicants have noted the numerous objections to the specification regarding the use of trademarks, and the minor informalities listed as (i) – (iii). Numerous trademarks have been amended to all-caps, and the minor informalities have been corrected.

35 U.S.C. 112, Second Paragraph Rejections:

Claim 41 was rejected under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Specifically, the Examiner found no support in the specification for the term “caprylocaproyl macroglycerides.” Claim 41 has been amended to delete this term in order to advance the prosecution of this application, and without conceding to the Examiners argument.

Claims 48-51, and 53 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite due to the use of the term “about” in connection with the recited numerical ranges. During the interview of September 12, 2005, the issue of the term “about” was discussed in terms of an entire range. The discussion pertained primarily to the use of the term “between about.” It was agreed that the Examiner would withdraw the 35 U.S.C. § 112 rejections if the word “between” was deleted. As such, Claim 50 has been amended accordingly. Regarding Claims 48-51, and 53, Applicants note that MPEP § 2173.05(b) addresses use of the term “about” and states that the use thereof has been held to be definite with respect to numerical ranges such as those in the present claims. It is generally accepted that this recitation provides flexibility to a numerical range endpoint by providing that room for a given value to be “a little above” or “a little below” the endpoint. As such, the Applicants respectfully request that these rejections be withdrawn.

Claims 36, 42-44, and 46 were rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter that the

Applicants regard as their invention. Specifically, the Examiner has alleged that the term “derivative” is a relative term that renders the claims indefinite. The Applicants respectfully disagree with the Examiner’s assertion. However, for the purpose of advancing prosecution in the present application, and without conceding the correctness of the Examiner’s position, Claims 36-46 have been amended to recited various specific derivatives of each stated compound. Reconsideration is therefore respectfully requested.

Claims 42-46 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite due to the use of the terms “slowly” and “high.” The Applicants believe that the terms “slowly dissolving salt complex” and “high molecular weight” are common terms to one of ordinary skill in the art, and would thus be readily understood. In order to advance the prosecution of the present application, however, the terms “slowly” and “high molecular weight” have been deleted from Claims 42 and 44 respectively. Reconsideration is requested.

Claim 42 was rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter that the Applicants regard as their invention. Specifically, it is the Examiner’s position that the term “insoluble carrier” is a relative term that renders the claims indefinite. The Applicants respectfully disagree with this assertion. Claim 42 contains the limitation that the release modulator may include, *inter alia*, an insoluble carrier. The term “insoluble carrier” should not be considered in a vacuum, but in relation to the term “release modulator.” A release modulator merely modulates the release of the drug being administered. Any range of insolubility that modulates such administration would be considered to be within the claim scope. Once in possession of the present disclosure, one of ordinary skill in the art would readily understand be able to formulate an insoluble carrier for a given active agent that would provide modulation of release without undue experimentation. It was not the

Applicants' intent to provide an exact range of acceptable insolubilities because variation of such provides a variation in the modulation of the release of the drug, and such insolubility variation would be understood by one of ordinary skill in the art. The Applicants respectfully remind the Examiner that it is not the public at large that needs to be informed of the boundaries of the claims, but one of ordinary skill in the art. In addition to understanding the basic principle of release modulation by an insoluble carrier, one of ordinary skill in the art would be further informed as to the nature of insoluble carriers through the examples provided. Accordingly, the Applicants respectfully request reconsideration of this rejection.

Claim 51 was rejected under 35 U.S.C. § 112, second paragraph, for allegedly failing to particularly point out and distinctly claim the subject matter that the Applicants regard as their invention. Specifically, it is the Examiner's position that the term "correlation coefficient" is a term that renders the claim indefinite because the specification lacks a specific mathematical definition of how such a coefficient is to be calculated. The Applicants assert, however, that one of ordinary skill in the art would be familiar with, and have the knowledge to readily calculate a correlation coefficient. As evidence of such, page 183 of Principles of Procedures of Statistics (hereinafter "Steel") is hereby submitted as Exhibit 1. Steel describes the correlation coefficient defined by equation 10.1, and provides sufficient detail that it may be readily calculated. Accordingly, it is the Applicants' position that such calculation is well within the knowledge of one of ordinary skill in the art, and as such, respectfully requests that the rejections be withdrawn.

Obviousness-Type Double Patenting Rejections:

The Examiner has rejected Claims 35-61 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over various claims of U.S. Patent Nos.

6,294,192; 6,569,463; and 6,720,001; and are provisionally rejected over various claims of U.S.

Patent Application No. 10/428,431, which has now issued as U.S. Patent No. 6,923,988.

Terminal disclaimers are filed herewith in order to expedite the present prosecution, without agreeing to the Examiner's assertions.

35 U.S.C. § 102 Rejections:

The Examiner has rejected Claims 35-52, 55, and 57-61 under 35 U.S.C. § 102(a) or 35 U.S.C. § 102(e) as being allegedly anticipated by U.S. Pat. No. 6,569,463 (hereinafter "Patel"). By the present amendment, the specification has been amended to correct the priority of the present application, as was discussed with the Examiner during the interview of September 12, 2005. As such, the present application now derives benefit from the Patel patent. Thus the Applicants respectfully assert that Patel is not available as a prior art reference against the present application, and these rejections have been rendered moot.

35 U.S.C. § 103 Rejections:

The Examiner has rejected Claims 35-61 under 35 U.S.C. § 103(a) as being allegedly unpatentable over Patel in view of U.S. Patent No. 5,403,593 (hereinafter "Royce"), U.S. Patent No. 6,458,373 (hereinafter "Lambert"), U.S. Patent No. 2,680,749 (hereinafter "Cawley"), and U.S. Patent No. 6,623,755 (hereinafter "Chen"). As has been discussed above, the present application as amended derives benefit from the Patel patent, and thus Patel is not available as a prior art reference to use in establishing a *prima facie* case of obviousness. As Patel is no longer available as a reference, the presently asserted combination of references is improper and the rejection therefore moot.

Accordingly, Claims 35-64 remain pending in the present application. In view of the discussion during the Examiner interview of September 12, 2005, Applicants respectfully submit

that the rejections of the presently amended claims are moot and that the claims are in condition for allowance.

**CONCLUSION**

In view of the foregoing, the Applicants believe that Claims 35-64 present allowable subject matter and the prompt allowance thereof is requested. If any impediment to the allowance of these claims remains after consideration of the present amendment and above remarks, and such impediment could be removed during a telephone interview, the Examiner is invited to telephone the undersigned attorney, so that such issues may be resolved as expeditiously as possible.

Please charge any additional fees except for Issue Fee or credit any overpayment to Deposit Account No. 20-0100.

Dated this 6th day of February, 2006.

Respectfully submitted,

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